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**A Method and Device for the Treatment of Obstructive Sleep Apnea and Snoring.**

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## FIELD OF THE INVENTION

The invention relates to methods and devices for the treatment of snoring and obstructive sleep apnea by retraction of soft tissue in the oral cavity and pharynx.

## BACKGROUND

Snoring and obstructive sleep apnea (OSA) are common disorders effecting hundreds of millions people worldwide. OSA and snoring are related to narrowing or obstruction of the human upper airway during sleep. Obstruction usually occurs in the posterior pharyngeal area due to the tongue or other soft tissues.

Benign snoring is a partial obstruction of the airway with vibration of the soft tissue. More severe obstruction causes louder snoring and decreased airflow, thereby disturbing sleep. Complete obstruction of the airway stops inspiration.

Sequela of snoring and OSA range from depression, difficulty concentrating, gastric reflux, hypertension, myocardial infarction and possibly cerebrovascular accidents.

At present therapy for snoring includes weight loss and avoidance of sedatives. Surgical procedures use laser or microwave energy to remove or stiffen tissues.

The primary therapy for OSA involves continuous positive pressure respiration (CPAP). This requires the use of a mask tightly attached around the nose and connected to a respirator. The positive pressure splints the airway open and is highly effective. Unfortunately, patient compliance is poor for technical or social reasons.

Surgical options for OSA include tonsillectomy, uvulopalatoplasty, tongue mass excision, mandibular or maxillary advancement, and finally tracheostomy. All these surgeries carry significant risks and other then tracheostomy, are only partially effective.

Invasive therapies undergoing development include implanted neuroprothetic devices that stimulate the muscles that move the tongue forward.

Clearly snoring and OSA are significant health problems and there is a need in the art for new and more effective therapies.

## OBJECT OF THE INVENTION

It is an object to provide a method and device for the treatment of OSA and snoring.

## SUMMARY OF THE INVENTION

The pathophysiology of sleep disorders is believed to be due to excessive soft tissue in the upper airway and particularly in the oropharynx, and specifically the base of the tongue the end of the soft palate and the lateral pharyngeal walls. Therapies have targeted reducing the amount of tissue in this area or moving the tongue forward to increase the dimensions of the airway. Unfortunately these have been only partially successful.

The recent fad of tongue piercing has shown that placing permanent metal objects through the tongue is well tolerated with few side effects. The conduit for the tongue stud is formed by passing a large bore needle through the midline of the tongue As the procedure is done by non-health care personnel no anesthesia is used. Despite this, and the contaminated oral secretions that diffuse through the conduit, the procedure is well tolerated and has few side effects.

The current invention would be to place and object (implant) in the oral cavity tissues that would pierce at least one mucosal membrane. The implant would function to retract tongue or other oropharyngeal tissue to prevent airway collapse, therby relieving obstructive sleep apnea and snoring.

## DETAILED DESCRIPTION OF THE INVENTION

The proposed device would retract tissues away from the area of obstruction during sleep. One embodiment of the device requires one or more attachment points made by piercing the mucosa of the tongue, palate, or pharyngeal walls. These attachment conduits could be left open during the day and a wire or similar retainer attached at night to retract soft tissue. To retract the soft tissue the other and of the retainer would attach to the teeth, a dental prosthesis, an external retainer, or through a second soft tissue conduit.

One embodiment might be an implant similar to current tongue studs. The shaft of the implant would pass from the midline of the dorsal surface of the tongue and exit the ventral surface. One side would have a widened terminal a flange or globular shape, while the other side could either have the same or an islet to which a an external wire or other item could be attached. One or both of the ends could be removed. The implant could be rigid and composes metal, preferably a non-reactive metal (stainless steel, titanium) or other rigid material. Or the implant could flexible and composed of rubber, plastic or similar materials.

The shaft could be solid or hollow, such that with the ends removed a line could be threaded through it.

The implant could have electrodes and stimulation electronics implanted to stimulate surrounding tissue. One embodiment would be to stimulate the genioglossus muscle to aid in tongue retraction. The implant could also contain biologically active agents. One embodiment might be a drug that stimulated muscle to increase their tone. Another might be a drug that acted to decrease tongue fat.

Another embodiment would have a drug that is useful for an entirely different purpose then sleep apnea. One example would be antibiotic that would release during the night to combat periodontal disease. Another embodiment might be a chemotherapeutic agent for cancer, or medicine for gastrointestinal tract or pulmonary disease. In another embodiment the primary reason for th device would be drug delivery and the device could be releasing a medication that diffuses into the oral cavity or through the walls of the conduit.

Areas through which the implant might be placed include the tongue, oropharyngeal hypopharngeal and nasopharyngeal walls, including the cheeks, hard and soft palate, and floor of the mouth. There may be one or more implants.

The implant may retract the tissue by itself because of the area it is placed or may be attached to an external anchor. These may be a dental device the teeth, another anchor, or external to the mouth.

The implant may be temporary or permanent. It is one embodiment that part or all be removed during the day and replaced at night. The tissue conduit could be kept patent by a second item placed after the implant removal that was more comfortable.

Example one

A sixty four year old male has OSA. He is treated by piercing his tongue in the midline from the frenulum through the midbase of tongue just posterior to the sulcus terminali. A 1" circular rubber flange is at the tongue base side. On the ventral surface a similar flange is placed. On each side a 1/4-inch metal ball is threaded. The total length of the shaft is 2 inches and the threaded ends are each 1/2-inch.

After placement and healing the device is used by screwing the globular ends so that the flanges are pressed against the tongue. On the dorsal surface the intent is to retract the tongue midline so as to produce a concavity that allows air to pass. A secondary effect is to make the structures rigid so that they cannot collapse or vibrate easily.

The ventral or dorsal globular screw can be entirely removed and a loop of wire or rubber can be placed and held secure when the screw is replaced this wire could be looped over the teeth or a dental retainer or passed external to the mouth. The length of the wire could be adjusted as needed.

After maturation of the conduit the entire device could be removed during the day, or could be replaced by a short flexible type shaft that was more comfortable.

Upon placement of the device the patient undergoes a sleep study where the effects of tightening the screws and/or the wire are measured until it the patient nolonger snores or experiences sleep apnea.

Example 2

A forty-year-old male snores loudly at night and has obstructive sleep apnea syndrome. On examination tongue size is within normal limits but an elongated palate is noted.

The patient has an implant inserted to treat his snoring. The implant passes from the anterior surface of the uvula through the soft tissue of the palate and exits through the oral surface of the soft palate just distal to the hard palate. The implant is made of very flexible material. The implant is as long as the tissue in its natural state such that it does not interfere with palate movement. The uvular end of the device has a soft circular flange 1/2 inch in diameter. The hard palate end has the same flange but it is not permanently attached to the shaft. The end of the shaft has a smaller 1/4 " flange and this can be grasped by the patient and pulled thereby tightening the shaft and displacing the uvular anteriorly and superiorly. A small clip can be place on the end of the anterior shaft at night to keep it in a shortened position. As the flange in this end is no rigidly attached the clip rests against the flange. The flexibility of the device is such that the patient can move his soft palate sufficiently to speak and swallow but enough retraction is open the airway and stiffen the tissues to prevent snoring.

What is claimed is all patentable advances over prior art.